CARESCAPE™ R860 Ventilator

Clinical Accessories Guide

GE Healthcare offers you a simple, reliable, one-stop solution for high-quality, OEM, GE Healthcare-compatible clinical accessories. We provide an expanded inventory of products that have been validated by our engineers. This guide is designed to help end users utilize our official clinical accessories effectively.

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Notice

The materials contained in this document are intended for educational purposes only. This document does not establish specifications, operating procedures or maintenance methods for any of the products referenced. Always refer to the official written materials (labeling) provided with the product for specifications, operating procedures and maintenance requirements.

Contents

Note! *Always refer to the User Reference Manual before use. Refer to the User Reference Manual for information on all warnings and precautions.*

Section 1:
Inspiratory Safety Guard

The Inspiratory Safety Guard (ISG) is required to connect the breathing circuit to the ventilator. The ISG must be used at all times during ventilation.

Installation and Replacement of the ISG

The ISG is a mechanical hydrophobic HEPA filter (not electrostatic) to help prevent patient gas from contaminating the inspiratory gas path of the ventilator. The ISG is attached to the inspiratory port of the ventilator as shown here (red box). It cannot be cleaned and does not have to be replaced between patients. However, it must be replaced when patient gas has passed through the safety valve. This can occur in the following situations:

- Excess or sustained pressure in the system, as indicated by the following alarm messages: Relief valve opened, Patient circuit occluded, Sustained airway pressure

- Failure of the air or O_2 supply gases while connected to the ventilator
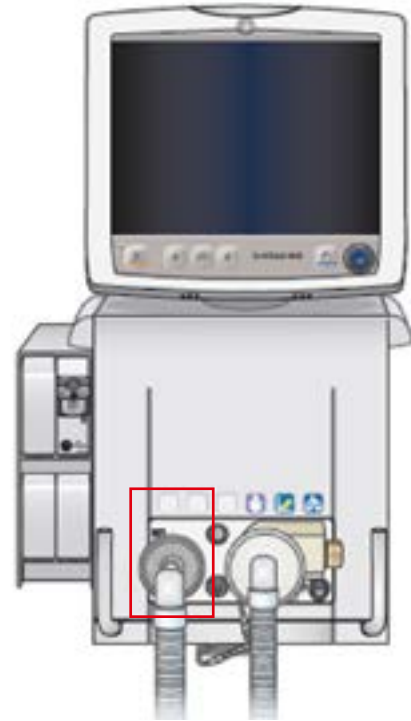
2066713-001	Inspiratory Safety Guard – Qty 1
2083208-001	Inspiratory Safety Guard – Qty 10

| Inspiratory Safety Guard Efficiency	
Efficiency	> 99.94% at a particle count at a size of 0.3 microns
Bacterial efficiency	> 99.999%
Viral efficiency	> 99.999%
Resistance to flow	< 1.5 cm H_2O at 30.00 + 0.15 l/min < 3.6 cm H_2O at 60.00 + 0.15 l/min
Filter weight	< 60 g
Internal dead space	< 85 mL

*May not be available in all regions.*

Section 2:
Exhalation Valve Assembly

The flow sensor is one of the most important components of your critical care ventilator. It automatically checks patient airway flow and pressure 250 times per second, making it the "eye" of your ventilator. Both reusable and single-patient-use EVA options are available.

The exhalation valve housing contains the expiratory flow sensor and water trap.

Connecting the Exhalation Valve Assembly

1. To attach the housing, place the tab (2) of the housing into the groove (1) and push the housing into position.
   - Listen for audible click and then gently pull on the housing to make sure it is securely latched
2. To remove the housing, press down (3) on the latch to release the exhalation valve housing and then pull the housing from the ventilator.
3. Unscrew (4).

May not be available in all regions.
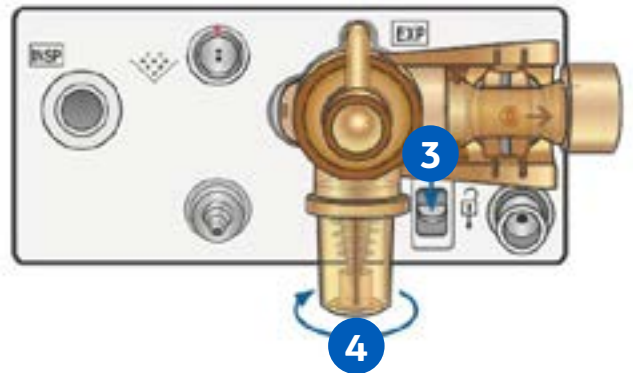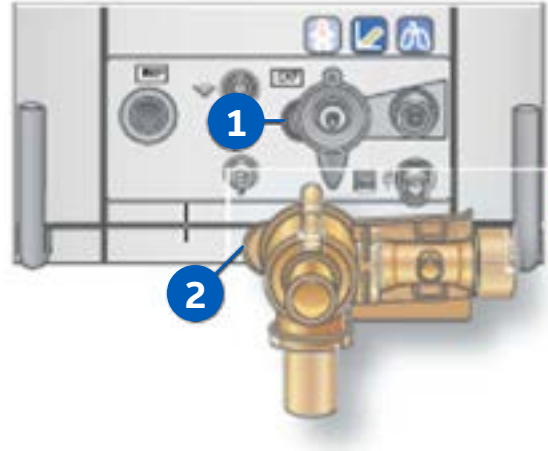
Single-patient-use Exhalation Valve Assembly and Flow Sensor

Our single-patient-use EVAs come in three different configurations and two different packaging levels to best meet your needs. The EVA and flow sensor can be purchased pre-assembled or separately, in cases of ten (10) or individually packaged.

		Part Number	Flow Sensor Included	Exhalation Valve Assembly Included	Pieces/pkg
Flow Sensor and EVA Kit		1505-3848-001	Y	Y	1
		1505-3848-010	Y	Y	10
EVA Only		1505-8568-001	N	Y	1
		1505-8568-010	N	Y	10
Flow Sensor Only		1505-3231-001	Y	N	1
		1505-3231-010	Y	N	10

Reusable EVA

GE Healthcare recommends you replace your Exhalation Valve Assembly (EVA) at a minimum of every twelve (12) months or a maximum of fifty (50) reprocessing cycles.

Note: *The EVA can be sterilized automatically at 134° C for 3-4 minutes with an autoclave or disinfected manually by soaking in denatured Ortho-phthaldehyde or Hydrogen peroxide (Sporox II). Please refer to the User's Reference Manual for details on this process.*

		Part Number
Reusable Flow Sensor (includes check valve and screen)		1505-3231-000
Exhalation Valve Kit with Flow Sensor		1505-3848-000
Exhalation Valve Kit without Flow Sensor		1505-8568-000
Diaphragm		1505-3224-000
Seal		1505-3223-000
Housing		1505-3222-000
Small O-Ring		1505-3056-000
Plunger		1505-3245-000
Spring		1505-3013-000
Large O-Ring		1505-3009-000
Water Trap		1505-3244-000

Section 3:
Exhalation Valve Heater

Use the exhalation valve heater to prevent moisture from condensing in the expiratory flow sensor when a humidifier is used.

The exhalation valve heater should be utilized when an active humidifier with a heated expiratory limb is used.

### Connecting the Exhalation Valve Heater

CAUTION: *Port 3 must only be used for connecting the exhalation valve heater cable.*

1. Attach and tighten the cable to port 3 on the back of the ventilator.
2. Thread the cable through the rear channel to the front of the ventilator.
3. Angle the cover over the exhalation valve housing and gently press into place.
4. Align and match the red dots from the exhalation valve heater cable to the power cable and snap together. Connecting the cable will power on the exhalation valve heater.

Note: *To disconnect and remove the exhalation valve heater, follow instructions in reverse order.*

Exhalation Valve Heater

1	M1200693	Exhalation Valve Heater
2	M1188723	Cable (order separately)
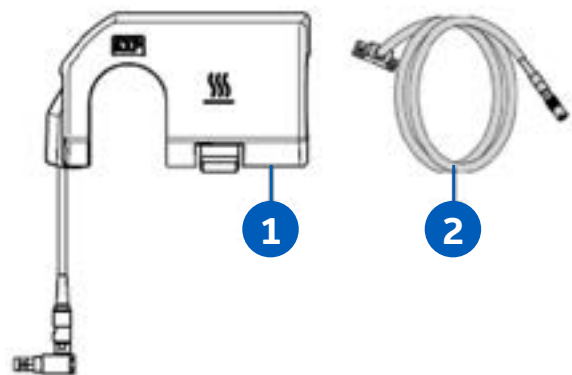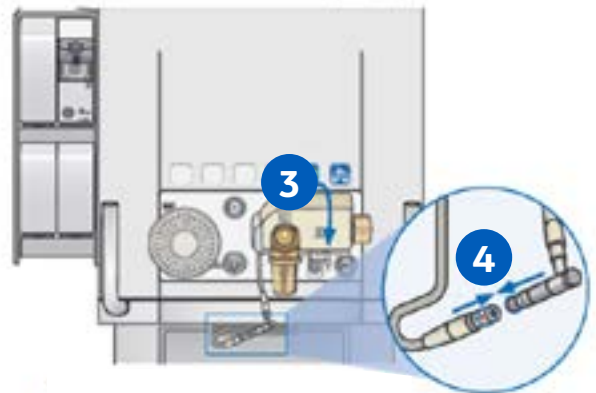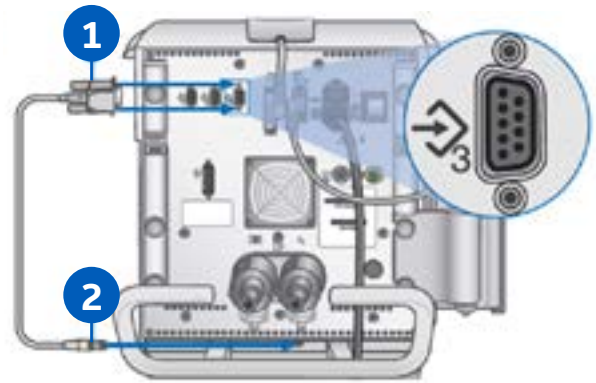
*May not be available in all regions.

Section 4:
Nebulizer*

The Aerogen® Professional Nebulizer System is a portable medical device for multiple-patient-use that is intended to aerosolize physician-prescribed solutions and suspensions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

The Aerogen Pro In-line Nebulizer and Aerogen Solo Disposable In-line Nebulizer may be used with neonatal, pediatric, and adult patients in acute and subacute care environments. Both nebulizer models operate without changing the patient ventilator parameters and can be refilled without interrupting ventilation.

The nebulizers may be used with a neonatal, pediatric, or adult breathing circuit. The T-adapter for the nebulizer is specific to the breathing circuit type.

WARNING: *Do not use a filter, heat-moisture exchanger or heat-moisture exchanger filter between the nebulizer and the patient airway.*

CAUTION: *It is strongly recommended to use an expiratory filter when a nebulizer is used to help protect the expiratory flow sensor. If the patient type is neonatal and a neonatal flow sensor is in use, remove it from the patient circuit during the delivery of nebulized medication and change the data source to ventilator to prevent damage to the neonatal flow sensor.*

Assembling the Nebulizer

WARNING: *Always maintain the nebulizer in a vertical orientation while it is in the patient circuit. This orientation helps prevent patient secretions and condensation from contaminating the aerosol generator of the nebulizer and ensures proper nebulization.*

1. Connect the nebulizer to the T-adapter by pushing the nebulizer firmly onto the adapter.

2. Connect the nebulizer and T-adapter into the inspiratory limb of the breathing circuit before the patient wye.

3. Attach the nebulizer cable to the nebulizer connection as shown, matching the red dots.

4. Complete a System Check prior to use on a patient. See "System Check" in the "Operation" section of the CARESCAPE R860 User Reference Manual for additional information.

5. Follow the "Nebulizer treatment" procedure in the "Procedures" section of the CARESCAPE R860 User Reference Manual.


*May not be available in all regions.

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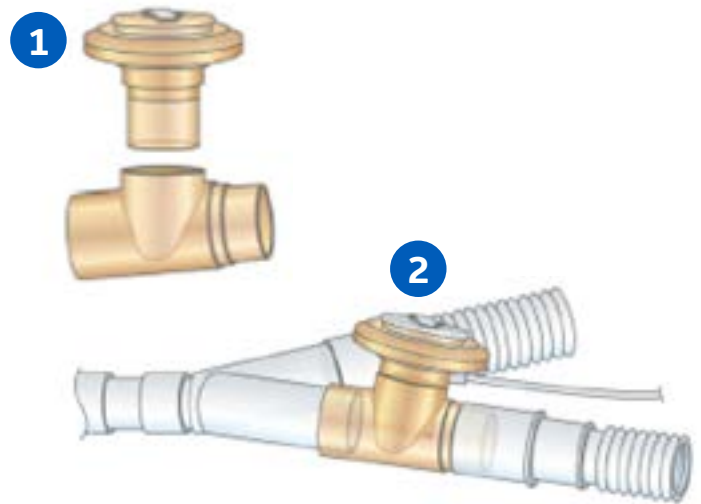
Filling the Nebulizer

CAUTION: *To help avoid damage to the nebulizer, do not use a syringe with a needle. Do not push or apply undue pressure to the domed aperture plate in the center of the nebulizer.*

The maximum capacity of the Pro nebulizer unit is 10 mL. The maximum capacity of the Solo nebulizer is 6 mL. Do not fill the nebulizer beyond the maximum fill indication point. The underside of the filler cap represents the maximum fill indication point.

1. Open the filler cap tab on the nebulizer.
2. Use a prefilled nebule or syringe to inject the medication into the filler port.
3. Close the filler cap tab.
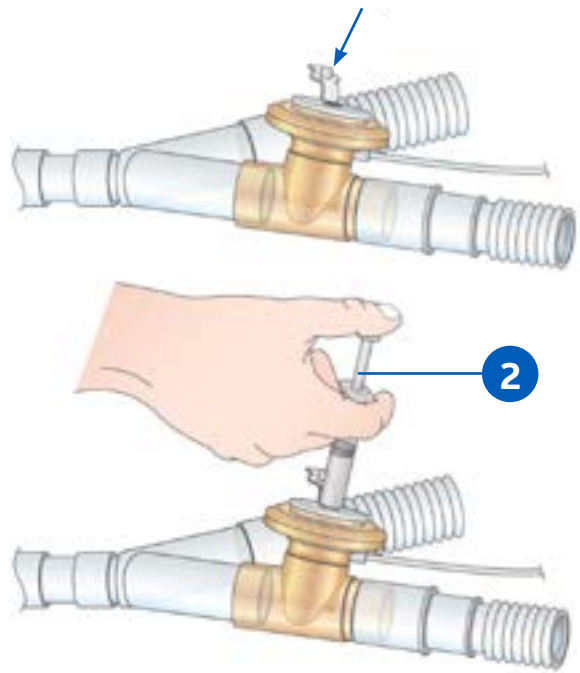
Disassembling the Nebulizer

The nebulizer and T-adapter may remain in the patient circuit when not in use. The nebulizer may be removed from the T-adapter and replaced with a plug to avoid leaks.

1. To remove the nebulizer cable from the nebulizer, grasp it close to the ventilator and pull straight out.
2. Remove the nebulizer and T-adapter from the inspiratory limb of the patient breathing circuit. Reconnect the circuit.
3. Clean and sterilize the Pro nebulizer and T-adapter as described in the "Cleaning and maintenance" section of the CARESCAPE R860 User Reference Manual.

Functional Test

Perform a functional test of Aerogen nebulizers prior to first use, after each sterilization, before each patient use, or at any time to verify proper operation.

Inspect all parts before use, and do not use if any parts are missing, cracked or damaged.

The time and approximate volume of nebulized medication are shown in the table. The calculated volume is based on an average nebulization rate of 0.38 mL/min, but the actual nebulization rate of each individual nebulizer cannot be guaranteed and may vary.

1. Visually inspect each part of the device for cracks or damage and replace if defects are visible.
2. Pour 1-5 mL of normal saline (0.9%) into the nebulizer unit.
3. Connect the nebulizer. Follow the instructions in Assembling the Nebulizer above.
4. Select **Menu** > **Nebulizer** > **Aerogen**.
5. Select **Time** > 16 minutes. The time and approximate volume of nebulized medication are shown in the table. Selecting Continuous will deliver nebulized medication until medication delivery is stopped or runs out.
6. Select **Start** and verify that aerosol is visible.
7. Select **Stop** to end the nebulizer treatment and verify that aerosol is not visible.
8. Discard any remaining liquid before patient use.

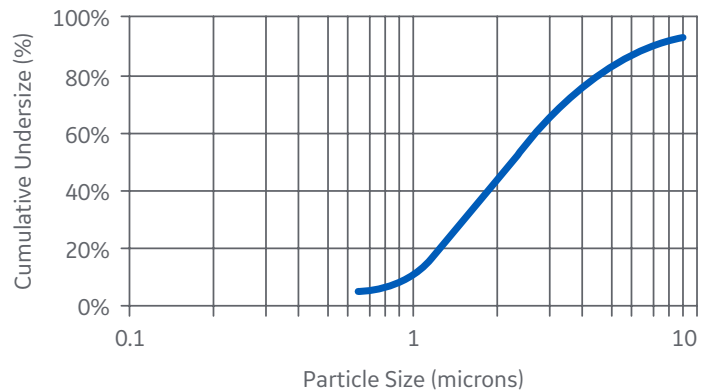| Time (min)	7	8	11	16	21	26	32
Volume (mL)	2.5	3.0	4.0	6.0	8.0	10.0	12.0

Nebulizer Specifications

The following specifications are according to Aerogen, the manufacturer of the Aerogen Pro and Aerogen Solo nebulizers.

Note: *The manufacturer does not recommend a minimum fill volume, but specifications which are tested with a minimum volume, use a volume of 2 mL.*

Aerogen Pro Nebulizer	
Maximum capacity	10 mL of liquid
Noise level	Less than 35 dB at 1 m distance
Temperature increase above ambient during normal use	Not more than 10° C (18° F)
Flow rate	Greater than 0.2 mL/min (average: 0.4 mL/min)
Mass Median Aerodynamic Diameter (MMAD)	• Average tested with the Anderson Cascade Impactor (spec range 1-5 μm) : 3.1 μm • Average tested with the Marple 298 Cascade Impactor (spec range 1.5-6.2 μm) : 3.9 μm
Aerosol output rate (starting dose of 2 mL)	0.24 mL/min
Aerosol output (starting dose of 2 mL)	1.08 mL
Residual volume (3 mL dose)	Less than 0.1 mL
Particle distribution (representative for Albuterol)	• 20% greater than 5 μm • 35% 2-5 μm • 45% less than 2 μm
Respirable fraction performance (% < 5 μm)	80%
Life of product	The life of the Aerogen Pro nebulizer and components have been validated for use by the manufacturer Aerogen for 730 doses and 26 autoclave treatments based on a typical one year usage profile of four treatments per day and one sterilization per week, where the device is assumed to be in service for 50% of the time. Note that any use in excess of this may result in reduced life of the nebulizer.

Representiative particle size distribution for Albuterol as per EN 13544-1 for use with the Aerogen Pro nebulizer

Aerogen Solo Nebulizer	
Maximum capacity	6 mL of liquid
Noise level	Less than 35 dB at 1 m distance
Temperature increase above ambient during normal use	Not more than 10° C (18° F)
Flow rate	Greater than 0.2 mL/min (average 0.38 mL/min)
Mass Median Aerodynamic Diameter (MMAD)	• Average tested with the Anderson Cascade Impactor (spec range 1-5 μm) : 3.1 μm • Average tested with the Marple 298 Cascade Impactor (spec range 1.5-6.2 μm) : 3.9 μm
Aerosol output rate (starting dose of 2 mL)	0.30 mL/min
Aerosol output (starting dose of 2 mL)	1.02 mL
Residual volume (3 mL dose)	Less than 0.1 mL
Particle distribution (representative for Albuterol)	• 35% greater than 5 μm • 30% 2-5 μm • 35% less than 2 μm
Respirable fraction performance (% < 5 μm)	65%
Life of product	• The life of the Aerogen Solo Nebulizer and components have been validated for use by the manufacturer Aerogen for Intermittent use for maximum of 28 days based upon a typical usage profile of 4 treatments per day • For continuous use, the life of the Aerogen Solo Nebulizer unit and the continuous nebulization tube set have been validated for use for a maximum of 7 days. The user should note that use in excess of these periods is not validated by Aerogen

| Nebulizer Replacement Parts	
1505-3846-000	Aerogen nebulizer kit, includes Adult and Pediatric tee
1505-56020999	Nebulizer cable (order separately)
AG-AS3450	Aerogen tee with plug
AG-AS3100-S	Aerogen Solo Nebulizer (5)
AG-AS3200-S	Aerogen Solo Nebulizer (10)
AG-AS3010	Aerogen Nebulizer tee, Adult (10)
AG-AS3020	Aerogen Nebulizer tee, Pediatric (10)
AG-AS3035	Aerogen Nebulizer tee, Neonatal, 12 mm M/12 mm F (10)
1505-5602-000	Nebulizer cable
AG-AP1030	Aerogen Nebulizer filler cap (5)
AG-AP1000	Aerogen Nebulizer head with filler cap
AG-AP1010	Aerogen Nebulizer tee-adapter with silicone plug, Adult (5)
AG-AP1100	Aerogen Nebulizer replacement kit, Adult (includes two nebulizer heads with filler caps and two adult tees)
AG-AP1020	Aerogen Nebulizer tee-adapter with silicone plug, Pediatric (5)
AG-AP1200	Aerogen Nebulizer replacement kit, Pediatric (includes two nebulizer heads with filler caps and two pediatric tees)
AG-AP1035	Aerogen Nebulizer T-adapter with silicone plug, Neonatal, 12 mm/12mm (5)
AG-AP1005	Aerogen Nebulizer, silicone plug
AG-AS3400	Aerogen Connection Luer

Section 5:
Humidifier

The ventilator is designed to work with active humidification. GE Healthcare recommends the use of the Fisher & Paykel MR850 humidifier (refer to humidifier instructions for detailed information on humidifier connections and use).

WARNING: *Never position any filter in the inspiratory limb downstream of a humidifier. When adding attachments or other components to the ventilator, the pressure gradient across the breathing circuit may change.*

Connecting the Humidifier

1. Slide the humidifier heater onto the accessory rail (do not plug in).

2. Press down on the light blue lever of the humidifier and slide the water chamber into the humidifier heater. Release the light blue part of the humidifier heater.

3. Unwrap the water feed line from the humidifier water chamber and puncture the water reservoir. The water reservoir should be elevated above the humidifier at all times and water should flow down into the humidifier.

4. Use the short blue circuit tubing from the humidifier circuit pack and connect one end to the Inspiratory Safety Guard and the other end to the appropriate port on the humidifier chamber.

5. Connect the longer piece of blue circuit tubing to the remaining port on the humidifier. Connect the end of the white circuit tubing to the expiratory port or expiratory filter (if used).

6. Connect the heater wire to the humidifier heater, then connect the two leads to the ends of the patient circuit (the shorter lead to the blue tube).

7. Connect the temperature probe to the humidifier heater, connecting the keyed lead to the end of the blue tube of the patient circuit and the other to the patient wye for adult (near the patient wye on the blue tube for pediatric/neonatal). The thermal operating temperature of the humidifier is 18-26° C according to the manufacturer.

8. Turn on the ventilator and perform the System Check. See "System Check" in the Operation section of the User Reference Manual for more information.

9. If the System Check passes, plug in the humidifier and attach the exhalation valve heater. See "Connecting the exhalation valve heater." To disconnect; follow the instructions in reverse order.
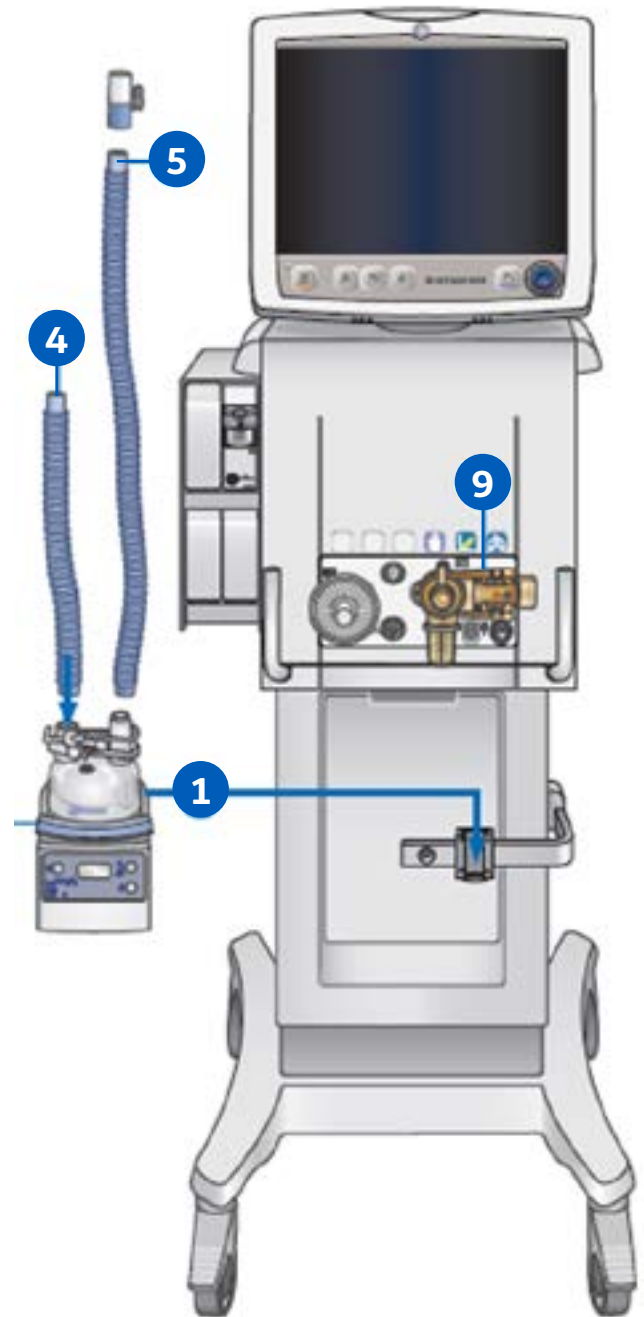
*May not be available in all regions.

Patient Circuit Connection with Humidifier Components

1. Humidifier (Fisher & Paykel)
2. Inspiratory Safety Guard
3. Inspiratory limb to and from humidifier to patient wye
4. Expiratory port/expiratory filter if used
5. Expiratory limb
6. Spacer (5 mL – minimum)
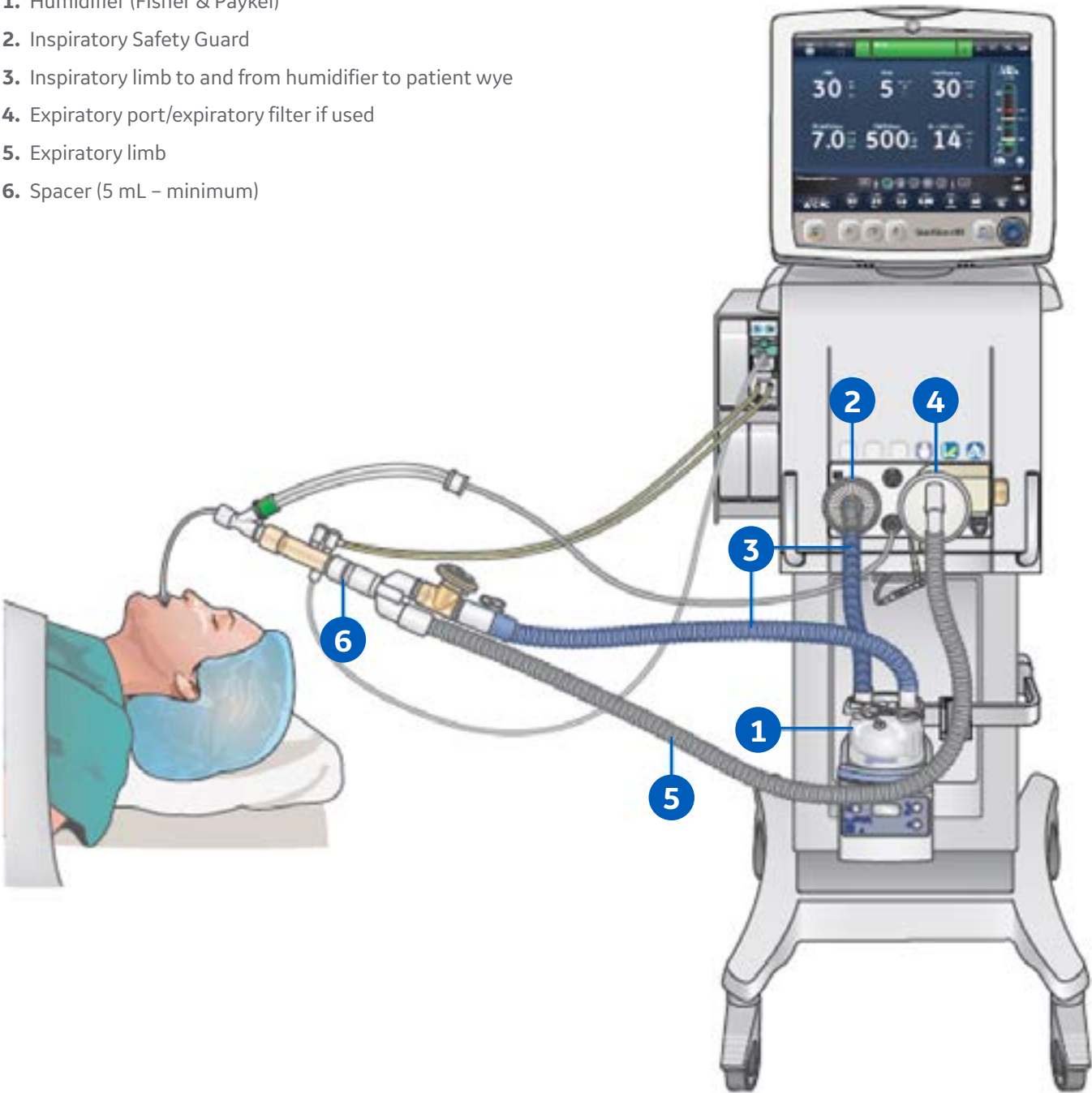
MR850	Fisher & Paykel humidifier, with heater wire (900MR805) and temperature probe (900MR869)
MR290	Fisher & Paykel autofill humidification chamber

Section 6:
Neonatal Flow Sensor

The neonatal option on the CARESCAPE R860 Ventilator provides ventilation for neonatal patients weighing 0.25 kg and above. Using an optional neonatal flow sensor at the patient wye, which connects to the ventilator with a cable, allows for more accurate flow and volume monitoring in the neonatal patient type.
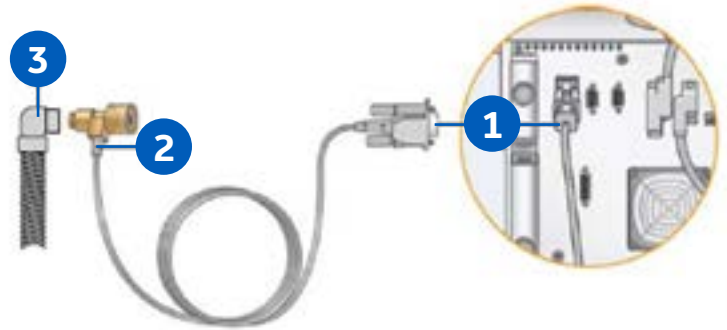
WARNING: *The neonatal flow sensor should be calibrated after every day of continuous use and after replacement.*

CAUTION: *Only utilize port 1 when connecting the neonatal flow sensor.*

Connecting the Neonatal Flow Sensor

1. Connect the neonatal flow sensor cable connector to port 1 on the back of the ventilator.
2. Connect the neonatal flow sensor to the cable.
3. Connect the neonatal flow sensor to the patient breathing circuit.
4. Connect the neonatal flow sensor to the patient airway connection.

Note: *To disconnect, follow the steps in reverse order.*

| 1505-5604-000	Neonatal flow sensor cable
1505-3272-000	Neonatal flow sensor

Calibrating the Neonatal Flow Sensor

The neonatal flow sensor can be calibrated automatically through the System Check or manually through the System menu.

WARNING: *Calibrate the neonatal flow sensor (NFS) after every day of continuous use.*

Note: *The neonatal flow sensor can only be manually calibrated when the neonatal flow sensor is not set as the data source.*

1. Select **Menu** > **System**.
2. Under Data Source, select **Ventilator**.
3. Hold the flow sensor between thumb and index finger to occlude both parts at the same time.
4. Under Calibration, select **NFS**. When the calibration is complete, a green check mark (pass) or red X (fail) will appear next to NFS.
5. Under Data Source, select **NFS**.
6. Connect the flow sensor to the patient circuit.

May not be available in all regions.

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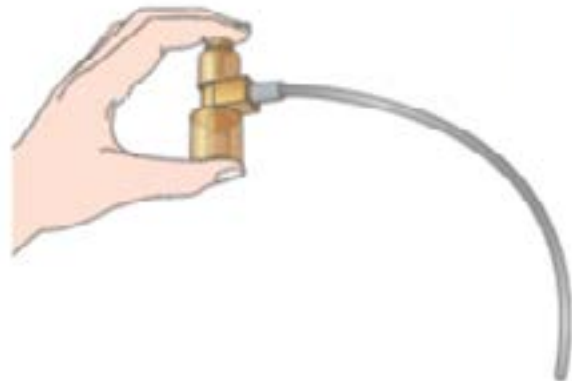
Section 7:
Part Replacement Schedule

The table shows recommended part replacement intervals. Replace the part at the interval listed or after the stated number of cleaning cycles, whichever occurs first.

	Interval	Reprocessing Cycles
Neonatal flow sensor	6 months	25
Expiratory flow sensor	6 months	50
Aerogen Pro Nebulizer and T-adapters	12 months	26
Exhalation Valve Assembly	12 months	50
Exhalation Valve Diaphragm	12 months	50
Cart-mounted water trap	*As needed	50
D-lite™ Sensor	*As needed	50
Pedi-lite™ Sensor	*As needed	50
Water trap connector tubing (hytrel tubing)	*As needed	50
Display and ventilator fan filters	*As needed	*As needed
Compressor air inlet filter	*As needed	*As needed
Inlet filter bowl	*As needed	*As needed

Visually inspect parts to determine if cleaning or replacement is needed. Look for deformation, cracks, or discoloration.

References:

REF: CARESCAPE R860 Ventilator PARTICIPANT GUIDE DOC1732630

REF: CARESCAPE R860 Ventilator User's Reference Manual 2065490-001 06 14 D